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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,257	02/08/2002	Boyong Li	141-242A	9034

96056 7590 12/13/2010

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
12/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/071,257	LI ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *WO 0059479*.

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimer filed on 10/07/10 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,589,553, 6,905,708 and 7,771,750 along with any patent granted on Application Number 12/835,863 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Midha et al WO 00/59479 hereafter '479 in view of by Percel et al US 2001/0046964.

The '479 patent discloses a pulsatile delivery composition comprising an immediate release components comprising an uncoated drug pellet (page 7, lin. 17-22, page 9, lin. 5-20); a

first coated pellet comprising the same drug and pH dependent polymers and a second pellet comprising water insoluble polymers (page 8, lin. 8-31). The pH dependent polymers include shellac, and polyvinyl acetate phthalate (page 8, lin. 20-24). The water insoluble polymers include ethylcellulose ethyl cellulose and cellulose acetate (page 8, lin. 10-15). The second coated pellet is designed for colonic release, meaning the pellets release in the intestine at pH above 70 (page 8, lin. 28-30). The composition can be a tablet or capsule comprising the three populations of drug particles (page 10, line 12-20). The drugs include a wide range of compounds including bupropion (page 13, line 20). Each portion comprises up to 100 mg of the drug (page 12, lin. 8-15). The second pellet is present in a concentration of half that of the first pellet (claim 9), meeting the ratio limitations of the instant claims. The formulation comprises tableting excipients such as diluents, binders and lubricants (page 11, lin. 15-23; page 11, lin. 1-29). The tablet formulation can comprise approximately 40% of a solid pharmaceutically acceptable tablet excipient such as microcrystalline cellulose (Example 1 and 2).

The reference is silent to the specific release kinetics of the instant claims; however it is the position of the Examiner that such limitations are dependent from the compositional components and specifically the disposition of polymers within the formulation. As such any dosage form with the same disposition of polymers would have the same release kinetics. As discussed above the dosage from of the '479 patent discloses a an oral capsule or tablet comprising an immediate release portion comprising uncoated drug particles, a first coated pellet comprising enteric polymers and a second coated pellet comprising water insoluble polymers that release the drug content in the colon. The enteric and water insoluble polymers are the same as the instant claims, with the ratio of the first and second coated pellets comparable to the ratio

of the instant claims. For these reasons it is the position of the Examiner that since the dosage form of the '479 patent discloses the same dosage form, with the same drug with the same disposition of polymers would have the same release kinetics as the instant claims. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The reference does not exemplify a bupropion formulation; however bupropion is listed as a possible active agent and bupropion is well known as a drug compo0und useful in pulsatile dosage forms. This can be seen in the '964 publication. The '964 publication discloses a pulsatile bupropion formulation comprising an immediate release portion and a coated sustained release portion (abstract, claims). It would have been obvious to substitute bupropion into the formulation of the '479 patent since the '964 publication discloses its use in pulsatile controlled release formulations.

With these things in mind it would have been obvious to follow the teachings and disclosures of the '479 patent to arrive at the formulation of the instant claims. The dosage form of the '479 patent discloses a capsule or tablet formulation of bupropion comprising an immediate release, enteric and pH independent portion that releases in the lower gastrointestinal tract. The dosage form comprising three separate portions that are combined into a singular dosage form that comprises the same coating polymers and tableting excipients, present in comparable concentrations as the instant claims. It would have been obvious to formulate a bupropion dosage from as seen in the '964 application, since bupropion is known to be delivered in a pulsatile format. One of ordinary skill in the art would have been motivated to follow the

disclosures and teachings of the '479 patent in order to arrive at a pulsatile dosage form with reduced risk of abuse.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618